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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,434	10/03/2006	Osamu Tsukada	Q93184	9992
23373	7590	10/03/2008	EXAMINER	
SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				TREYGER, ILYA Y
ART UNIT		PAPER NUMBER		
3761				
			MAIL DATE	DELIVERY MODE
			10/03/2008	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/568,434	TSUKADA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ILYA Y. TREYGER	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 October 2006.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-7 is/are rejected.
- 7) Claim(s) 5 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

1. Claims 1-7 are examined on the merits.

### ***Response to Arguments***

2. Applicant's arguments filed 06/16/2008 have been fully considered but they are not persuasive:

Applicants argue that the two-part structure of Cohen et al. differs from the one-part structure of the present invention, which combines the balloon and reservoir and branching unit on a single integral catheter body.

However, it has been held that forming in one piece an article which has formerly been formed in two pieces and put together involves only routine skill in the art.

*Howard v. Detroit Stove Works*, 150 U.S. 164 (1993)(**MPEP 2144.04 (V-B)**).

Applicants further argue that the one-part structure in the present invention also operates differently from that of Cohen et al.

The difference in operation between the present invention and Cohen depends of the particular location of the on-off valve. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to locate the on-off valve as claimed, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70 (**MPEP 2144.04 (VI-C)**).

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

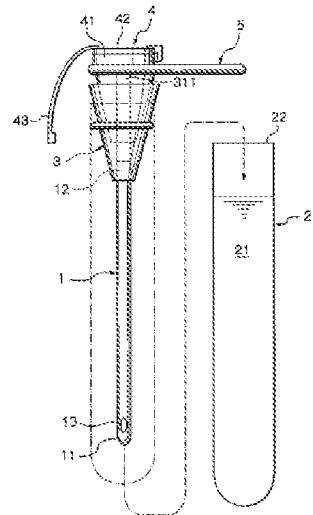
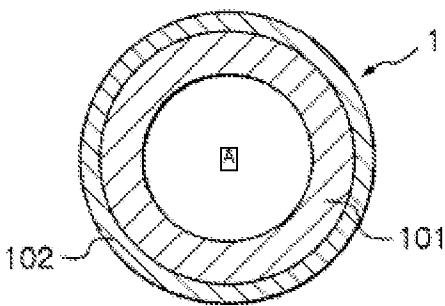
6. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukada et al. (US 6,695,831) in view of Cohen et al. (US 6,162,201).

7. In Re claim 1, Tsukada '831 discloses an intermittent urethral catheter set comprising a catheter unit 1 (Fig. 1), a disinfectant casing 2 (Fig. 1), and a cap 41 (Fig. 1);

Said catheter unit including: a catheter body 1 (Fig. 1) having an urine-guiding passage A (Fig. 4), a plug (holder) 3 (Fig. 1) attached to an intermediate portion of the catheter body; reinforcement tube 101 (Fig. 4) inserted into the interior of said urine guiding passage in said catheter body (Col. 2, ln. 44-47).

disinfectant casing 2 being detachable fitted (Col. 2, ln. 39) on said plug in a sealing manner for containing a lower part of the catheter body below said plug and for storing a disinfectant liquid (Col. 2, ln. 40);

the cap 41 being detachably fitted on a top portion of the catheter body for opening and closing an outlet port (ol. 2, ln. 41-42).

*Fig. 1**Fig. 4*

Tsukada '831 does not expressly disclose the water-guiding passage; a balloon attached to a distal end of the catheter; a branched tube bifurcated from the catheter; a reservoir attached to a free end of the branched tube; and an on-off valve attached to the branched tube.

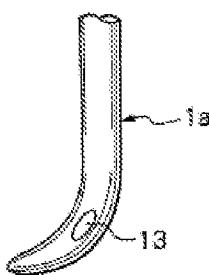
Cohen teaches that it is known to use in the urinary catheter the water-guiding passage 42 (Col. 4, ln. 20-24; Fig. 2) that extend along a longitudinal direction of the catheter and is separated from the urine-guiding passage; a balloon 24, 26 (Col. 4, ln. 3-4; Fig. 1) attached to a distal end of the catheter in an inflatable manner; a branched tube B (Fig. 2) bifurcated from the catheter body; a reservoir (Col. 4, ln. 20-21) attached to a free end of the branched tube; an on-off valve in fluid communication with the fluid passage (Col. 2, ln. 4-6).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the urethra catheter set of Tsukada '831 with the water-guiding passage; a balloon attached to a distal end of the catheter; a branched tube bifurcated from the catheter; a reservoir attached to a free end of the branched tube; and an on-off valve attached to the branched tube, as taught by Cohen, because such modification would provide the catheter with improved retention features.

Tsukada '831 /Cohen do not expressly point out the attachment of the valve to the branched tube. It would have been obvious to one having ordinary skill in the art at the time the invention was made to attach the valve to the branched tube, because the relocation of the valve of Cohen from the one liquid passage to another liquid passage is the matter of optimization. Rearranging parts of an invention involves only routine skill in the art.

8. In Re claim 7, Tsukada '831 discloses the catheter set, wherein a distal end of the catheter body is formed into a curved configuration (See Fig. 5).

*Fig. 5*

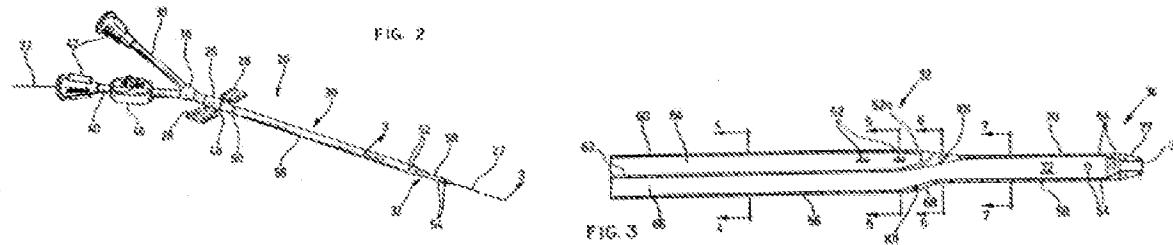


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9. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukada et al. (US 6,695,831) in view of Cohen et al. (US 6,162,201), as applied to claim 1 above, and further in view of Martin (US 5,188,593).

Tsukada '831 in view of Cohen disclose the invention discussed above, except for the branched tube that is detachably connected to the catheter body.

Martin teaches dual lumen catheter wherein a branched tube is detachably connected to the catheter body (See Figs. 2 and 3).



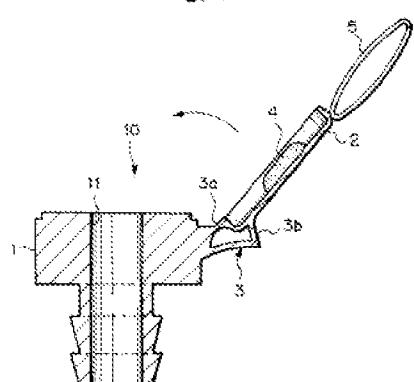
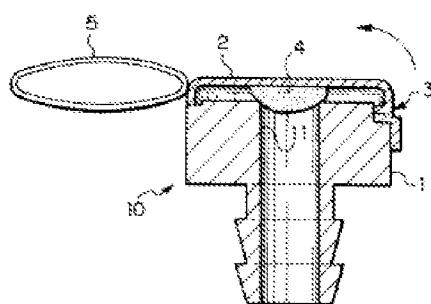
It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter set of Tsukada '831/ Cohen with the branched tube detachably connected to the catheter body, as taught by Martin, because such modification would provide the catheter set with repair capability.

10. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukada et al. (US 6,695,831) in view of Cohen et al. (US 6,162,201), as applied to claim 1 above, and further in view of Tsukada (US 5,817,067).

11. In Re claim 3, Tsukada '831 in view of Cohen disclose the invention discussed above, except for the catheter set, wherein said cap includes a connection plug body, a hinge section, and a lid that are made of a synthetic resin material integrally together with one another, wherein

an engaging member made of a flexible material is mounted on a central portion of an inner surface of said lid, and wherein a pull string is attached to an end of said lid.

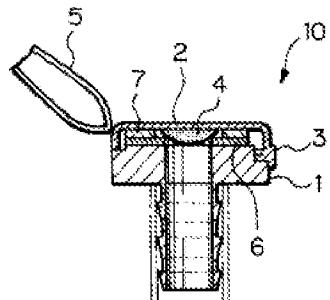
Tsukada '067 teaches that it is known to use the cap 10 including a connection plug body 1, a hinge section 3, and a lid 2 that are made of a synthetic resin material integrally together with one another, wherein an engaging member 4 made of a flexible material is mounted on a central portion of an inner surface of said lid 2, and wherein a pull string 5 is attached to an end of said lid 2 (See Col. 3, ln. 14-19; Col. 4, ln. 18; Figs. 1 and 4).

*Fig. 1**Fig. 4*

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the catheter set of Tsukada '831/ Cohen with the cap design, as taught by Tsukada '067 , because such modification would improve the antiseptic features of the system.

12. In Re claim 4, Tsukada '067 teaches that it is known to use the catheter, wherein the cap includes a first annular magnet 6 secured to a top surface of the connection plug body and a second annular magnet 7 secured to an inner surface of the lid to surround the engaging member (See Col. 1, ln. 66-67; Col. 2, ln. 1-2; Fig. 9).

*Fig. 9*

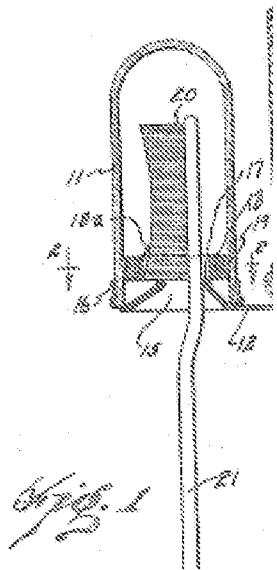


It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cap of Tsukada '831 with the magnetic closure, as taught by Tsukada '067, because such modification would improve the efficiency of the device.

13. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukada et al. (US 6,695,831) in view of Cohen et al. (US 6,162,201), as applied to claim 1 above, and further in view of England (US 1,486,957).

Tsukada '831 in view of Cohen disclose the invention discussed above, except for the absorbing material mounted on an inner peripheral surface around an upper outlet of the disinfectant casing.

England teaches that it is known to use mount the absorbing material 18 on an inner surface around the outlet 15 of the disinfectant container (casing) 11 (See Fig. 1).



It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the disinfectant casing of Tsukada '831/ Cohen with the absorbing material, as taught by England, because such modification would provide the casing with the additional disinfectant carrier.

#### *Allowable Subject Matter*

14. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. The specific limitations of "valve body which includes a recess that supports said plunger to permit said plunger to reciprocate in said recess with a frictional resistance, a first tube communicated to said reservoir, and a second tube communicated to said branched tube, wherein said plunger includes a plunger body that can reciprocate in said recess with a frictional resistance, a flange, and a communication hole", are not anticipated or made obvious by the prior

art of record . For example, the reference US 6,162,201 teaches a valve used in the urinary catheter.

However US 6,162,201 fails to teach or suggest the specific limitations of the valve body including a recess that supports said plunger to permit said plunger to reciprocate in said recess with a frictional resistance, a first tube communicated to said reservoir, and a second tube communicated to said branched tube, wherein said plunger includes a plunger body that can reciprocate in said recess with a frictional resistance, a flange, and a communication hole.

### ***Conclusion***

16. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILYA Y. TREYGER whose telephone number is (571)270-3217. The examiner can normally be reached on 7:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ilya Treyger/  
Examiner  
AU 3761

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761